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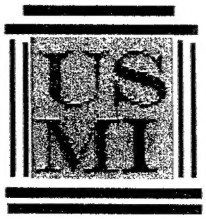

The U.S. Medicine Institute
For Health Studies

Redacted Proceedings — Forum for Decisionmakers

Weaving A National Surveillance System — The Role of Federal Healthcare

Washington, D.C.
March 6, 2003

Executive Summary

The nonprofit **U.S. Medicine Institute for Health Studies** on March 6, 2003, gathered decisionmakers from government and the private sector to examine the need for a national surveillance system and how such a system might best be developed, given current, often disparate, attempts at various levels of disease detection.

Opinions presented at this forum ranged from assertions that "we have a long way to go" in developing a national system to reassurances that a national surveillance system in fact exists in the form of the current process for reportable diseases overseen by the Centers for Disease Control and Prevention. The prevailing view, however, was that disease surveillance, to be useful, must be real-time, must be automatic and must be standards-based — and undoubtedly will rely on DNA sequencing chips that can screen for a vast array of organisms.

There was hopefulness that the focus on bioterrorism will infuse neglected public health systems with new resources, yet caution that placing too much emphasis on bioterrorism could prove counterproductive in the long run, in that funding likely would dry up should no incident occur within the next several years.

These edited proceedings present the remarks of panelists at the forum and the ensuing discussion among participants. Among the observations presented during the group's deliberations:

- The new Department of Homeland Security, along with the Department of Health and Human Services, will be key in establishing a national approach to disease surveillance. Just how all elements and levels involved in surveillance will be coordinated remains to be determined.

- Both the Defense and Veterans Affairs departments have large care-delivery systems and defined populations that can be used to evaluate data management for disease surveillance.

- Syndromic surveillance, as exemplified in the ESSENCE system developed by the Defense Department with civilian partners, is now in place in several regions of the country. Lessons from these initiatives will help in shaping a national system.

- A test now taking place at Lackland Air Force Base in Texas, with support from the Defense Threat Reduction Agency, will evaluate the efficacy of using an "adeno-chip" to detect adenovirus disease among recruits in comparison with standard diagnostic methods. "This is going to be an exquisite and wonderful clinical trial to actually try these technologies in the clinical setting."

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- An effective national surveillance system will become "part of how we deliver health care, day in, day out" and "part of how we treat infectious diseases, day in, day out." Being able to do this, however, is not immediately achievable.

- Timely communication between the various elements and levels involved in surveillance is key.

- A major challenge for syndromic surveillance will be to separate "the wheat from the chaff," that is, to "minimize the amount of wasted effort on following false signals."

- Numerous commercial chip-based systems are being developed and marketed. A "Consumer's Reports" type of organization is needed to evaluate and rate these products. National standards for defining and communicating data are needed.

- Locking into a single system at this point in time is "not a smart decision," because much experimental effort still is taking place and new insights may still "bubble up."

- Automated surveillance is "much more than an exercise in pushing electrons around. We need to learn what electrons need to be pushed, where they need to go, how to quality-assure them, how to push that analysis to somebody who can react on it, and how to motivate the person to react on it when he or she gets it."

- Should a bioterrorist attack occur, a concurrent cyber-attack could bring down automated disease detection systems. Backup systems are essential.

- "The use of existing electronic data for public health surveillance is here to stay — not for bioterrorism, necessarily, but for everything else."

- A national surveillance system involves more than data exchange: "It's about the relationship we're building between public health and clinicians."

Forum Proceedings

Introduction — John S. Zapp, DDS
USMI Managing Director

To officially inaugurate our program today, it's a pleasure for me to introduce our moderator, John S. Parker, M.D., who's a senior vice president at SAIC and former commander of the Army Medical Research and Materiel Command.

He's a native of Quincy, Massachusetts, a graduate of Washington and Jefferson College. He entered military service in 1963, received his doctorate of medicine, cum laude, from Georgetown University, his surgical internship and general surgical residency in thoracic surgery from Walter Reed Medical Center. He currently is leading SAIC's effort in supporting the national homeland defense initiative in the area of chemical and biological defense, public health, and biosurveillence, as a member of the Homeland Security Coordinating Committee. John is a very apt person to moderate a very apt topic for today.

Moderator — John S. Parker, MD

Today we are going to be talking about medical surveillance. We are talking about surveillance and where surveillance fits into this picture of our day-to-day healthcare, our public health mission, that we must face directly today and not just because of bioterror or terrorism. We must face the fact that a public health infrastructure — and understanding what public health is versus day-to-day medicine — is an important accomplishment that must occur at this crisis point in our nation.

Then as we move from those two entities — basic medical care, public health — how do we take both of them and perhaps expand the capability of the astute physician by using information technology, information management, good communication to give us earlier warning on an aberrant event, so that we can use traditional techniques to see if the event is natural,

manmade, or unknown and represents an emerging infection that we know nothing about.

Panel 1: What are the desired goals and attributes of a national surveillance system?

Col. Patrick Kelley, MD — *Director, Global Emerging Infections Surveillance and Response System, Department of Defense*

Kristi Koenig, MD — *Director, Emergency Management Strategic Healthcare Group, Department of Veterans Affairs*

Klaus Schafer, MD — *Public Health Advisor, Chem-Bio Directorate, Defense Threat Reduction Agency*

Robert Pinner, MD — *Director, Office of Surveillance, National Center for Infectious Diseases, Centers for Disease Control and Prevention*

Patrick Kelley:

This morning I will share with you some personal views of how the federal sector may be able to contribute to the development of an improved national public health surveillance system sensitive enough to facilitate a maximally effective response to outbreaks of bioterrorism and other emerging infectious diseases. Though my views do not necessarily reflect the official position of DoD, I've had the privilege to develop them over the last five years as the director of the Department of Defense Global Emerging Infection Surveillance and Response System, and as part of my role as director of GEIS, I've overseen the development of ESSENCE, the Electronic Surveillance System for the Early Notification of Community-Based Epidemics.

ESSENCE is our nation's largest syndromic or health indicator surveillance system, and its scope and intensity provide us a rare opportunity to define many pertinent issues in this field, which still is not what I would call a field without many skeptics.

The threat of emerging infections in general, and the unique epidemiologic characteristics of bioterrorism in particular, have now made public health

workers agents of the national security community. Recognition that life, liberty, and the pursuit of happiness are now subject, on a massive scale, to malevolent, insidious, epidemiologic threats mandates a renewed public health system to defend against these threats.

In crafting defenses against bioterrorism, the United States has made substantial progress, for example, in acquiring smallpox vaccine for primary prevention. However, primary prevention has its limits. So, secondary prevention, based on early detection and response, is something to be sought as an important supplement.

Environmental sensors to detect released agents have captured the imagination, but they have limitations for blanket national or even blanket local coverage. The implication, thus, is that frequent, even 24/7, clinical surveillance may be central to a nationwide early detection system. A more traditional approach to surveillance — weekly or monthly reporting — clearly would make epidemiologists historians rather than proactive instruments of public health. A further challenge is that traditional surveillance has focused on the reporting of specifically defined, usually familiar and confirmed reportable conditions whereas emerging infections, including bioterrorism, can involve less familiar and poorly characterized threats.

Constant 24/7 surveillance is a new challenge for the public health community, and again, as I would say, it remains in the eyes of many to be proven as something useful.

Given that the federal government's proper role is national security and the regulation of interstate issues and that a bioterror attack clearly is not only an interstate issue but also one of international dimensions, our government at the federal level has a clear responsibility for this form of surveillance. The national dimension of any attack, and the value of a coordinated national information system and the novelty of the approaches that we're considering, demand not only federal funding but also federal leadership.

The Departments of Health and Human Services and Homeland Security are the key leaders in establishing a national approach to this form of public health surveillance. But, optimal leadership includes leading by example. Since neither of these departments has an inherent patient care base sufficient to develop model approaches to innovative national surveillance,

it's natural for the DoD and the VA to supplement this experience with the millions of patients that we have under our care and thus contribute to the overall federal leadership effort.

What can Defense and the Veterans Administration actually contribute? Well, first by having automated medical systems that document medical encounters through ambulatory records, through in-patient records, through pharmacy records, through nurse hotline records, through laboratory records, we can apply basic startup data to explore the utility of a national surveillance system.

If you will allow me to be a little generous, ESSENCE is already something of a national system, capturing every day the morbidity experience at hundreds of Department of Defense clinics around the United States. More accurately, though, our data do fall short of what is needed for a national system, because they provide highly variable coverage of the country and constitute a sampling fraction overall of less than 5 percent of Americans. We might have excellent coverage for an attack on basic training using Great Lakes Naval Training Center near Chicago, but we don't add much to help detect an attack on Los Angeles.

The heterogeneity of our DoD ESSENCE system is such that we anticipate optimal performance in geographically dense DoD settings, such as basic and training camps. More dispersed, more heterogeneous settings like Fort Bragg or Fort Hood, though, are a bit more of an epidemiologic challenge, and an even more dispersed civil military integrated setting, like the national capital region, presents a greater challenge still, because in this national capital region, we only have about one out of 10 people who are eligible for care within the military health system.

One potentially powerful contribution, though, of DoD data in some critical regions, like the national capital region, and one which many civilian systems appear to be having trouble matching, is that we can actually geocode active-duty personnel not only by their usual residence location but also by their usual work site. Since an attack at the work site is far more likely than a residential exposure, being able to characterize ill individuals by where they work helps reduce geographic misclassification of an exposure and strengthens the signal of an outbreak.

A critical dimension of ESSENCE development has been military-civil partnerships to improve system performance. With DARPA funding, we've partnered with the Johns Hopkins Applied Physics Lab and others to create the beginnings of an integrated civil-military system for the national capital region. DTRA has also funded a similar ESSENCE collaboration with civilian systems in the Albuquerque area. These initiatives are showing how various data sources — federal, local, and proprietary — can be integrated for a common goal. Before a truly national system is established, it's critical to integrate lessons from these initiatives.

A value of ESSENCE, vis-a-vis other noteworthy nonfederal systems under development, is the sheer magnitude of DoD patient visits captured every day. This level of throughput has allowed a rapid identification of operational issues and suggested many solutions as to how to effectively protect patient privacy; how to group diagnoses into optimally sensitive and specific categories; how to mathematically separate normal trends from abnormal ones; and how to automatically summarize, display, and prioritize far more data each day than a human can otherwise handle.

With so many diverse communities under DoD surveillance, it's possible to develop insights into which lessons learned are generalizable and which ones are not. The fact that the MHS [Military Health System] is global, yet responsive to a single command-and-control focal point, allows data management changes to be made rapidly and evaluated. As such, the MHS can be a valuable test bed for evaluation of new surveillance ideas in a variety of situations.

One of the biggest challenges for a national system, and one of the biggest sources of my own tempered skepticism, is that of the implied response. Alerts generated by surveillance of this type are rarely clear-cut. Often the responses will end up being classified as false alarms, though often ones which can carry some lessons to be learned. While a nationally centralized analytic focus may be the heart of national surveillance, the initial response will almost always be at the local or state level for both practical and constitutional reasons. While in the strategic defense paradigm, rapid response to threats is taken for granted.

In public health, especially at the local level, 24/7 operations are not common nor are local health departments often set up to communicate with

the ease, security, and reliability needed to face these new requirements. As DoD works to match its internal public health response capability to the 24/7 demands generated by ESSENCE, exportable methods are being defined that may help make the response demands put upon civilian public health agencies more manageable.

In summary, DoD has valuable experiences to share relevant to the establishment of national real-time surveillance for events of public health importance. Some of its assets are unique, and many of the opportunities it presents as a large, distributed community under a unified, relatively automated healthcare system can help refine legal issues, help select data sources and analytic methods, and help project resource requirements for expansion of the system potentially on a larger scale.

These issues need to be addressed before the federal government tries to persuade nonfederal entities to join in the unproven enterprise of a rapid, accurate, and useful national public health surveillance system. DoD will be an invaluable test-bed to efficiently address the concerns of a range of skeptics, reassure privacy interests, and strengthen the credibility of the government as it sails through these poorly chartered waters.

Kristi Koenig:

Surveillance is not VA's primary mission; veterans care is our primary mission, and so it becomes a great challenge for us to participate in this when in the papers every day we're seeing veterans waiting six months for appointments and that type of thing. On the other hand, we do have a unique opportunity because we have a large, integrated national healthcare system, and in fact in our surveillance system we are covering about 1 percent of the U.S. population across the entire country.

It's a somewhat unique population. We don't see too many children, for example, in VA, but still it's a very large database that we would like to try to take advantage of and partner with our colleagues in DoD and CDC. We have a number of ongoing discussions and a lot of irons in the fire with this type of partnership.

At the current time, what VA does is collect data nightly across the entire system, but it's not actually reviewed except on a monthly basis, because it would be very labor intensive to look at things on a day-to-day basis. We do take an all-hazards, comprehensive emergency management approach. That's the philosophy.

We don't single out funding bioterrorism, for example. We're looking across the entire spectrum. We'd like to detect naturally occurring pandemic flu just as we'd like to detect an outbreak of something having to do with bioterrorism. We have to look at the entire public health system and not focus on just weapons of mass destruction. We also have to look at meeting any type of legal requirements — do we have authority to participate in these partnerships; are we complying with HIPAA, the new privacy rules for electronic transmission of data?

We have used our system with a proof of concept, looking to see if we could collect data on a 24-hour basis real-time rather than waiting 'til the end of the month: We had a hepatitis C surveillance day during which we went to see how many patients had actually been tested. It worked very well with good data validation.

One of the things that we've been doing is that through my office we have a technical advisory committee looking at how to prepare VA for any type of weapons of mass destruction event. Dr. Gary Rozelle, who's our infections disease chief, chairs a task force specifically looking at surveillance and was doing this well prior to this becoming a popular issue.

What we've put in place on the short-term basis — and this is available on our website — is something called "surveillance interrogatories." The idea behind an interrogatory model is we're not going to give you the answers, but we're going to give you a list of questions. At the local VA medical center level, you take these surveillance interrogatories and go through this list of questions — who do I call at three in the morning if I have a suspicious case? How do I connect with CDC? How do I connect our lab with another lab who might be able to verify what this is? Who do I contact both within my own chain of command and outside the medical center? Those answers may be different at different local levels.

We've put together the questions, that if you sit down with the people involved at the local level and partner with your community, you will have a

good system in place because, as was mentioned, communications is going to be really a key. Probably the first time we'll see something is on CNN these days rather than through our normal chain or command. We have to have good communications, good risk communications, in terms of advising people what to do if we detect something.

We may detect something through one of these syndromic surveillance programs, but another likely scenario, as happened in the anthrax cases, is the astute clinician who sees a case of smallpox or suspected smallpox. What do you do with that? You could close down an entire facility — and this has happened — if you see a case of suspected smallpox if you don't have good communications and coordination in place to do the verifications and make the appropriate notifications.
So, in addition to our partnership with DoD and CDC elements, we are also looking at training for our individual clinicians. How do we recognize potential cases that we have never seen perhaps before?

In summary what we're doing on the short-term is that we have surveillance interrogatories in place at the local level as part of our comprehensive approach. It's in a guidebook that we've put out for all our medical centers that looks at how you deal with any type of emergency. And then we are actively participating — looking at partnerships with HHS, with DoD, in terms of how we can contribute to the national effort on surveillance.

For those of you who want to look at our website it's *www.va.gov/emshg*. The surveillance interrogatories and the guidebook are posted on that website.

Klaus Schafer

The Defense Threat Reduction Agency and DARPA together funded a proposal back in about 2000 at the end of the Defense Science Board Review — summer review on bioterrorism. There were some recommendations that came out of that, and I will step through those for you.
One of the things I was involved in very early on was the concept called "health surveillance and biodefense system report" and also in trying to push this particular concept. I'm very much a pragmatist. As a clinician, we have

to understand the healthcare process from the point of service. that's really where it happens. If we're going to do any early diagnosis it has to happen at that point, it has to be reported at that point, and that's how we have to define any kind of surveillance system. Those are the concepts that I'm a big believer in, and of course this is the Schafer opinion and doesn't necessarily apply to any particular agency.

I mentioned that it was in 2000 that the Defense Science Board commissioned a study. That study basically made some recommendations based on existing science today in genetic sequencing and what was available in the scientific community and what was available in the informatics side of the house, basically putting a concept together of doing surveillance with a large informatics system and a network, and on top of that, using DNA sequencing and using those DNA fingerprinting tools to be able to do early diagnosis.

It really becomes a point-of-service kind of tool that allows a clinician to establish whether someone has an infectious disease or whether it's a threat agent, for instance.

The recommendation that came out of the group said, "Hey, the technology is available today. If DoD would get on it and commit some dollars, and on top of that they have this beautiful population called TriCare, that maybe, you know, this would be the place to try it." Obviously the TriCare population — many dependents and so on, and we get into the privacy issues — really wasn't going to play too well. What happened out of this study — they suggested that for about $3.5 billion the whole system could be built. It could be deployed in or across the three services and we would have the system up and running. And within DoD the discussion was, "Well, wait a minute, not so fast, let's commission a study on this and let's do a feasibility study." That's when DARPA and DTRA both were tasked to put together a study and take a look at the technology, the legal issues, and so on.

In fact, if one is able to collect information at the point of service, we start to notice that patients, once they develop symptoms, are going to appear in the healthcare system somewhere. That's the first event. Today, all the surveillance systems we have in place don't start at that point; they start further down the road, and most of them are built around ICD-9, and, you

know, the data's old. Now, it's good, useful data for doing epidemiology and doing other studies.

We have to figure out how to move that curve to the earlier point, and the thing that is important in doing that is HL-7 messaging in hospitals. As a clinician, if the patient comes in to me on day one and says, "I have the following symptoms," andas a doctor I say, "Well, I think it's one of these," they throw some antibiotics on that patient and I really don't know what I'm treating. It's best guess, okay?

An astute clinician and the anthrax case: Perhaps two days later if they order lab results you might get the actual definitive diagnosis, at which point they change the antibiotics, call the patient back in, and so on. Those are temporal relationship kind of events that are significant if you're doing surveillance. But we're not capturing that information today.

There were basic assumptions in the model as it was looked at. The real assumptions really revolve around the fact that healthcare remains very fragmented. It's still very difficult to pull all the pieces together to do a large surveillance effort. And I have to give credit to ESSENCE and GEIS, because they've done a marvelous job in at least pulling a network together to collect data. But as we all admit, we have a lot further to go.

Point of service really is where these things happen. But, we can't mess up the work flow of the doctors. We can't mess up the work flow of the nurses and the technicians twho are working in emergency rooms and clinics. We have to figure out how to capture that data around them. What has to come out of any surveillance system is decisions that become actionable decisions, meaning that if I'm the clinician I need to decide whether this is real. Is this anthrax or not anthrax? Is this adenovirus or not adenovirus? What am I going to do to intervene? If it's a significant enough event, is this something where I need to call in extra help? Today those processes exist, but they are slow. Again, it depends on the astute clinician to decide whether he needs to call in help or not.

Any system we put into place needs to have that kind of capability. If we're really intelligent about putting a system into place, we do it day in and day out. It becomes part of how we deliver healthcare day in and day out, and it becomes part of how we treat infectious diseases day in and day out. The

models that get built really have to depend on these kinds of issues, and we still have a long way to go, I believe.
Basically, most of the study objectives are feasible today. We can go down this road, and we should move forward aggressively. The sad part about being in DTRA is that there was initially money, but some of that money got pulled back, so this research hasn't gone forward. But it's where I think we need to go. There will be people who disagree. There will be people who say some of the tests are really not proven yet. And, yet, the point is when one asks how long does it take to get the results from a piece of laboratory information, before I can make a decision on what to do we have to ask that question.

Let's talk about mosquito tracking and the results from mosquitos before one decides to spray for mosquitoes. I just found out recently in New York that cycle takes 45 days. And why does it take 45 days? Because the mosquitoes are ground up, the samples are collected, they're sent to the central ;ab, and 45 days later here they come, and a decision is made to spray. Well, a lot happens in 45 days.

The point of any surveillance system really ought to be about, "when am I going to make a decision to do something?" If it's not about that then why have a surveillance system?

Panels created in this study included a medical panel, a legal panel, a technology panel, and an informatics panel. Each of the panels made its various recommendations, all of which basically boil down to the fact that this all doable today: Build a network, and build the tools to do rapid diagnostics at the point of service. That's doable. It's going to be expensive, but it's doable. The positive thing out of that is that it may actually be cost-neutral in the long run, because you can have an impact on certain things like antibiotic resistance patterns and treating patients with the right antibiotics at the right time.

An interesting aspect was the legal points of view. They felt there were some of these techniques that are being worked today, with gene sequencing and host-response done on biochips. They recommended that DoD probably not go there because of obvious reasons. The recommendation was to stand up an ethics board to really look at these issues.

Another interesting thing was that the medical panel initially wasn't that keen on it, particularly the ER docs — the reason being that "You're going to mess up my workflow. I'm too busy. I don't have time for this stuff. Don't waste my time. Give me something that really works." Until 9/11 hit. This report actually came out in December, two months after 9/11, and all of a sudden the docs all did a 180 and they said, "We need to go in this direction." It was pretty amazing.

The study really was done by a group out of Lincoln Labs. It was the MIT crowd and a number of other specialists that were brought in to do evaluations.
The actual technology that was looked at was felt to be pretty advanced, ready to go, and there were issues with intellectual property rights and things like that. They also did a complete survey of existing surveillance programs at the time. It was really quite a good study, I felt.

As DTRA looked at this, there were certain components that the Defense Threat Reduction Agency, because it is a science and tech agency for combatant commanders, felt that belonged in its sphere of influence and other components that it felt really belonged to the medical community. So, advanced diagnostics and advanced chip work could actually be done by the Defense Threat Reduction Agency and the people it contracts with or DARPA or similar agencies. But once you move into the healthcare side of things, it's in the healthcare arena. All those HIPAA issues, for example, need to play out in that arena.

Whether an incident response is in a local community, with the mayor and his EMS groups, or whether it's in the military command and control agencies, that falls outside the purview, in many cases, of the medical community. Any system we design has to consider all those pieces, and I'm not sure we do that just yet. Many of us are very focused on just the medical surveillance for the medical community, but let's not forget all the rest of the stuff out there.

Remember, my bottom line is that it's about making decisions, and it's about making decisions quickly and effectively and responsibly.

What was interesting about the current state of the art of diagnostic chips is that with about 400,000 wells on a single chip you can do a lot of DNA sequencing. It's amazing. You can do subtypes and you can do antibiotic

resistance, and you can put all that on chips. There have been discussions, I think, with NIH to move in this direction pretty quickly. These chips really are, we felt, the real future.

Today, PCR devices are pretty large, but they are portable. What was used in the post office environmental sampling were portable devices, and they were effective. There are false positives in anything you do, but it's how you handle a false positive that becomes the important issue. The concept that DTRA had was the distribution of these kinds of devices far out into the periphery where they become, as the computer geeks say, "edge devices". They're out there collecting data and feeding it back locally, regionally, and then centrally. If it's done right and the policies are put in place, then you don't get people jumping the gun and making decisions on false positives, because you're going to get them.

Then there is other work going on in proteomics and so on, and the sophistication of the technology really is truly incredible. The problem — and the reason we haven't adopted these new technologies in the clinical setting is — one, we've got to get them through FDA, and the other is there are no incentives, financial incentives for any hospitals, clinics, or anywhere else to put screening tests in place.

So, we need some legislative changes. What should those legislative changes be? It seems to me that we ought to be able to reimburse for these types of tests, and they ought to be reimbursed for any suspicion of an infectious disease. We ought to be able to run these kinds of tests.

Why are chips the way to go? Chips are based on silicone. Chips, if you produce lots of them, become very cheap, so although the initial tests will be very expensive, in the long run they'll be very inexpensive, and they should become very routine tests. The second piece of that is, we ought to put legislation in place that reimburses facilities to auto-report data to the public health system. Give them a little kicker of a buck or two and let them get paid to submit the data, so that for those docs and teams that don't always submit the reports into the health system, it would happen automatically. Technically, there are ways to blind the data, secure the data, make it HIPAA compliant, and do all those things. So there's no reason for us not to go down this road.

Interestingly enough, the Air Force did move forward on at least a first phase. DTRA funded some of this work, and they're in the process of putting together a network at Lackland Air Force Base, which is a recruiting center. They're focusing on adenoviruses, the first effort. What's interesting about this is adenovirus vaccine production got stopped. Adenovirus has an attack rate of 30 percent or so in recruits. Because of that, because of the complication rate, we're probably going to see one or two deaths per year in our recruit population. That's not good.

So, they decided to create an adeno-chip and put it in the clinical setting, and basically they're going to report out in the peer-to-peer reviewed community the results of this. They're going to do the chip test, then they're going to use standard PCR, and then they're also going to do the viral cultures and report that back out. I think this is going to be an exquisite and wonderful clinical trial to actually try these technologies in the clinical setting. The data will be reported through a reporting network, which is, I think, very interesting.

Chip readers are expensive. Today they're about a hundred thousand a piece. But, in the clinical setting you can run an awful lot of infectious disease stuff, and my bet would be that you would recover savings on the clinical side in the hospitals, because you're going to treat with the right kinds of things, right kinds of antibiotics. You're going to have less antibiotic resistance in that facility, because you're going to pick the right thing; you'll have fewer bad reactions to the wrong antibiotic. It's just better medicine. It's better quality medicine if you employ these kinds of techniques.

One proposal is for a four-year advanced concept demonstration. That's been delayed, but I suspect it's going to happen at some point in time.

Robert Pinner:

I will present some perspectives and some vignettes that together I think address some of the issues of what a national surveillance system ought to look like. Surveillance is a process that involves input and analysis and feedback. It also involves multiple sources of information. Its purposes include not just outbreak infections, but also trend analysis in monitoring the impact of intervention.

Who uses surveillance for which purposes varies, depending on whether you're sitting at the local level or the state level or the national level. There's a context for this. There's a clear national interest to promote the general welfare clause in public health. But the Bill of Rights delegates principal responsibility for public health surveillance and response to the states.

The way programs in public health are funded provides challenges. Our funding is by and large categorical. This is very good to focus activities in particular categories but provides lots of challenges to integrating across systems.

One attribute is skilled, attentive people, as shown in these three examples. There are lots of others:

1) Thursday, October 4th, 2001, just 24 days after September 11th, the Florida Department of Health and DDC confirmed the first case of inhalational anthrax. Recognition of this unexpected case is attributed to the alertness of local infectious disease physician Larry Bush.

2) In 1993, cases of acute illness characterized by fever, myalgia, headache, and cough followed development of rapid respiratory failure. This is hantavirus.

3) In August of 1999, an infectious disease physician from a hospital in Queens contacted the New York health department. And this, of course, is West Nile virus.

After anthrax cases were recognized in southern New Jersey around Trenton, there were 240,000 emergency department visits and 7,000 ICU visits monitored for syndromes that could have been anthrax. It wasn't clear what the extent of the cases was, and it wasn't so clear how they were going to present. As it happened, there weren't additional cases, but this kind of labor-intensive effort was necessary to define what was going on.

In the old days, and not-so-old days — sometimes still present days — in public health surveillance, data flow in individual, categorical systems up and down that are not interconnected, not talking to each other. A slightly more formal way to think about this in a context that we're emphasizing at CDC now is the context of a public health information network linking health departments, clinical care, state and federal agencies, and law enforcement in a standard- based architecture that Dr. Schafer alluded to.

There are lots of examples of technology starting to bear fruit. A couple of years ago in the Hawaii Health Department — which in truth was an easy target, it's confined to some islands and there are fewer labs to deal with — in a project in electronic laboratory-based reporting, they had two and a half times the number of reports. They got them faster and they were more complete. This is an example of the promise of this kind of electronic laboratory-based reporting but also other clinical reporting as well.

Algorithms exist for aberration-detection to detect outbreaks. TA simple example of mapping is found in GIS mapping of the floor of the Hamilton Postal Distribution Center in Trenton. Dots represent places where environmental samples were taken, with red dots ones that cultured positive for *Bacillus anthracis*, showing I think a concentration of the positive cultures around where the sorting facilities were. That's also where the cases occurred, where the persons presumably were exposed to those cases.

Another example of mapping — simple, straightforward, not a complex algorithm but illustrative and important nonetheless — involves post offices that were sampled in the Trenton area, 50-some-odd. Five red ones show where there was one swab that was positive, showing that spores had been distributed in the area, although I don't think that accompanied much in the way of health risk. But the point of showing the distribution is still there.

Here are several examples from our emerging infections program network, a network of 10 state health departments together with their academic collaborators, which does active laboratory-based surveillance and a variety of other activities for invasive pneumococcal disease:

1)After conjugate pneumococcal vaccine was licensed, some preliminary data show decreases in disease in children in multiple age groups, from '98 to 2001, hinting at an a vaccine effect.

2)Changes in cases per hundred thousand by serotype of pneumococcus. The biggest decreases in vaccine serotypes, one of the seven types included in the vaccine, are not totally expected, and there is very preliminary decrease in some vaccine-related strains and not much in non-vaccine strains. This is a tidy summary, but it rests on active laboratory-based surveillance that involves collecting information about the people, who they are, how old they are, where they live, but also rests on collecting isolates and serotyping, doing molecular and other work on those isolates.

3)The incidence of meningococcal disease in Oregon compared to the United States during the '90s, showing a substantial fivefold increase for a couple of years and then decreasing back toward baseline. The point of this is, it looks here like an increase in meningococcal disease, but in fact it was an increase specifically in serogroup B meningococcal disease and, more specifically, in a particular clonal group of serogroup B meningococcal disease.

This kind of surveillance is what's needed to be able to make these kinds of judgements. As it turns out, this clonal group of serogroup B meningococcus had been observed to cause prolonged periods of increased rates in other places in the world previous to that.

Here are some quick suggestions about what's potentially different or distinguishing about thinking about terrorism surveillance: They always have a high profile, even if the number of cases isn't high. Their very acute events set a premium on trying to work in real-time. And they have to link closely to response. In the anthrax cases, detecting them and doing surveillance for cases was a first step. But very soon thereafter it got into issues of targeting folks for prophylaxis and then following folks to look for adverse events.

Small events have big ramifications needing flexible, high-capacity ways of looking at them. I hate to use the word "paradigm, but here's the way we're thinking about this. Most of the surveillance I've been talking about, obviously, is at the point of diagnosis. There's theoretical interest and appeal to both trying to do surveillance at the point of syndrome onset and then, even further back, at the point of release of an agent. And while these are potentially valuable, there is lots left to learn about how and under what circumstances they would be most effective.

Respiratory syndromes, like anthrax or some of the other things we present, can be very common syndromes. They are essentially undifferentiated. They may have lots of day-to-day and week-to-week and season-to-season variations, and so figuring out how to separate the wheat from the chaff and really minimize the amount of wasted effort on following false signals is going to be the principal challenge for syndromic surveillance, I think. If that's a little bit on the speculative side, I think bio-detection, while

interesting and with lots of work going on to explore it, lots of work remains to be done.

Surveillance needs to be targeted to the situation that you're in, in the epidemiology of a disease. When polio was quite prevalent, a surveillance case definition and methods that only picked up cases of acute flaccid paralysis would have a high predictive value, if you will, for cases of polio. As vaccine was implemented and cases became more rare, keeping the predictive value positive of your surveillance required closer confirmation that it was polio. And now, when it's near zero incidence, not only do you need to do culture confirmation but you also need a way to sort out vaccine from wild-type infection.

Discussion

John Parker: My question to the panelists is that if we look at bio-detection and then come a little closer in and look at syndromic pickup and then look at diagnosis as our pickup, where are we in our level of confidence at any of those levels, if we had the best reporting system in the world? I mean, starting from the one that we think should be very, very good — the diagnosis by the astute healthcare provider — what's our confidence level at that, and if that confidence level is very good, what do you think our confidence level would be if we pushed the curve to the level?

Kristi Koenig: I don't think our confidence level is great right now. Having a surveillance system in place is one of the first steps, but it's very labor intensive to have somebody on a real-time basis evaluating those data and making decisions.

I think we're still in the arena of false positives and false negatives, perhaps in either case. I mean, take the idea of the astute clinician. When people get more interested in this, which usually happens after an event like the anthrax attacks, they pay more attention to it and they're more likely to report things. A lot of those things are not necessarily what they might be, and it can cause significant disruption. There are cases in the New York City area where hospitals were closed down temporarily, because there was a suspected case of smallpox, even though it turned out not to be.

So, I think we actually have quite a long way to go, and we really have to look at how we are going to evaluate the data, who's responsible for that, how that's going to be reported. Some of this can get into areas of national security, so we deal with issues of having to use caution with how we communicate things and who has a need to know and the informal communications channels in addition to the formal communications channels. We're in a state of huge transition in this country with the Department of Homeland Security just standing up, and there are processes that have been in place for many, many, many years that are now in a state of flux. So, I think we're really in quite early stages with a lot of this.

Robert Pinner: The time distance between syndrome and diagnosis isn't fixed, and at least as interesting to me are efforts to take the diagnosis point and move it back closer to the point of syndrome presentation — rapid diagnostics, if you will — as are efforts to employ statistical methods on undifferentiated syndromes.

Patrick Kelley: One could spend a little bit of time here, I think, discussing some of the definitions. We call ESSENCE and many other systems syndromic surveillance systems. In some respects, though, we actually take whatever the ICD-9 diagnosis is and move backward and group those diagnoses into syndromes, in part because different physicians presented with the same patient provide different diagnoses. Some will say you have the flu; others say you have a viral illness. Some will say have you have a cough and a fever — that's one reason why we kind of move backward and lump things.

I've been a bit frustrated for a while about the definition of an astute clinician, and I wonder how many clinicians are astute. We saw examples of the gentleman in Florida with anthrax meningitis, but I think we know that a number of people had cutaneous anthrax from the outbreak and were diagnosed before the gentleman in Florida, and somehow those cutaneous cases didn't bubble up, as far as I know, in the public health system. We know with West Nile, before that astute ID doctor in Queens, I believe it was, put two and two together and got worried, other people were being diagnosed with West Nile in New York City and they slipped through the cracks. I don't know for sure about hantavirus in the Southwest, but I wouldn't be surprised. If you were a great archivist, you could go back and probably find cases of hantavirus before that, too.

Robert Pinner: In fact during hantavirus, someone at CDC who had worked on an outbreak 10 years earlier — there was autopsy tissue — went back and in fact it was hantavirus. The only point I was making wasn't that there aren't better ways to do this, it was that it seems to me the phrase "acute clinician" — it's sort of shorthand for judgements that are not so easily algorithmizable.

Klaus Schafer: My view on this is that we need to eventually and fairly quickly get to molecular-level diagnostics, and that's going to be the real key to any kind of system. I believe we ought to go ahead and start to at least lay the framework in, whether it's syndromic surveillance or whatever, to build the networks. Otherwise, we may never build the networks.

I think there's value in just going through the exercise, although having had experience with syndromic surveillance and a tremendous amount of variability in that kind of data, I'm not sure that data is going to be very useful. We ought to collect it; we ought to go back and look at it; we ought to look at algorithms; we ought to do the scientific studies to see if there's any value in it. But I think we need to drive, eventually and as quickly as we can, to molecular-level diagnostics in an integrated surveillance system.

Nancy Tomich: I'm with the U.S. Medicine Institute. Who's going to make the decision as to what system becomes the standard and how we proceed with it?

Klaus Schafer: If I can just tackle that, I think it's a great question, and it's a great question because you've got multiple vendors out there; you have multiple universities out there; you have multiple government agencies all trying to create systems. What has to happen is the government, for one, needs to just basically define the standards, and CDC is doing a great job of that with their NEDS effort. It basically lays the framework for reporting systems.

But because of the way the money flows, decisions tend to be local decisions, and sometimes you get local solutions. So, standards-based is the key I think.

Robert Pinner: I agree with that. It's not about a vendor or a software application. It's about the interoperability you need to send messages back and forth, so the crux is identifying, promoting, and then helping folks to

implement the standards-based approaches, unless you're in a place where you have one system and you don't have to worry quite as much about it.

Kristi Koenig: With the Department of Homeland Security coming online, and some of these issues certainly involving national security, it's not entirely clear what role they might take as opposed to the traditional role taken by HHS. There are over a hundred different systems out there, and there are people at the local level who don't want to wait for national solutions and integration of all these different systems. This is a very, very key question that's not entirely answered.

Patrick Kelley: I would emphasize there's an immense amount to learn. These systems are much more than an exercise in pushing electrons around; we need to learn what electrons need to be pushed, where they need to go, how to quality-assure them, how to analyze them once we get them, how to push that analysis to somebody who can react on it, and how to motivate the person to react on it when he gets it, or she gets it.

My guess is that ultimately the Association of State and Territorial Epidemiologists may play a big role. As Bob noted, you know, this traditionally is a responsibility of states under the Constitution, and states may require entities to report. Right now we have reportable diseases, but I don't know that we have any reportable syndromes. If we're going to have a national system that is a serious one, it probably is going to require the states, which have the constitutional power to do it, to require entities, laboratories, and other healthcare-providing entities to report something. I tend to think a lot of it would be done in collaboration with the state and territorial epidemiologists. In the interim, there'll probably be a lot of interim decisions, because some people feel comfortable moving ahead with, if you'll excuse me, the half-baked systems that we have out there, and I would include my own as half-baked. Then there are others who are more prudent, maybe, or have less money or are more skeptical, and they're going to wait for a while.

Robert Pinner: There are things that can and should be done at the national level to facilitate this. Identifying and promoting the standards is one thing, but also investing in activities as resources allow and providing the technical assistance to ensure things unfold in a coherent way. Also, looking at existing national sources of data, if only 1 percent or 5 percent, to learn what we can learn from them at a national level is effort well worth it.

Kristi Koenig: Just a quick followup on the reportable diseases. Although there is some national standardization, these do vary by state, so that's one issue. Also, we come back really to the fact that I believe we need an automated system. Clinicians in this day and age in particular are just too busy to take time out and do something new or separate. It needs to be hooked onto something that's already being collected in terms of the data.

I'm an emergency physician by training. I can tell you that a lot of emergency physicians don't necessarily know what the reportable diseases are and may assume that somebody else is reporting them or they just simply ,ay not have time, with patients who may be literally dying in the hallways, to take time out and report something.

I really think we need to look at automated systems.

Robert Pinner: At least for clinical laboratory reporting, there is some electronic reporting going on now, and we're on the verge I think, of working with the larger national labs, of really doing this in a larger volume pretty soon.

Cathy Rick: I'm Chief Nursing Office for the Department of Veterans Affairs. My comments relate to encouraging us to always look at the essential elements of partnership between the medical and nursing communities when we look at topics like this. I appreciate Col. Kelley's emphasis that it's clinical surveillance, not just medical surveillance, that enters into the formula for addressing these challenging issues.

The "astute clinician" is something that jumped out as I heard that being discussed, because the federal nursing service chiefs, which I'm a member of, are challenged with developing appropriate strategic goals, and action items related to those goals, to enhance the astuteness of nurse clinicians in the area of surveillance — surveillance for an all-hazards approach, if you will. AI don't think that we've stepped up to the plate with meeting that challenge as yet.

I'm assuming our academic partners and affiliates will help us with that, but I do think that this is a significant piece — I welcome your comments or reactions to broadening the discussion to all of the disciplines that contribute

to all clinical surveillance. I think of other disciplines as well, but I'm wearing my nursing hat, so I'm speaking for nursing.

John Parker: Well, your point is well taken. The word "astute" sometimes is caveated by the word "physician," and it misses the point of the astute healthcare provider. Now, what does that really mean? I'll give you my definition of how I feel about this. I've been in the weapons of mass destruction business for 30 years. Twenty-five of those years, most of the nation didn't care; it was only a military thing. And within the military, there was the standard practice of healthcare and then there were the diseases, nuclear and chemical, that were over in this other bin that were not within the standards of the practice of healthcare.

I think the transition today as we talk about the astute healthcare provider is that the expectation of myself or yourself detecting a diabetic in the population — we should be able to detect an abnormal pathogen or an emerging infection just as well as we're diagnosing diabetes or hypertension or heart disease. It should be part of the standard of practice. It's sort of bringing it in, so that that knowledge base is global, and when something happens within the knowledge base, then we all know where to communicate to and how to communicate.

Cathy Rick: If you use the diabetic example, that extends to our responsibilities to entertain the public as to what are those key factors that they need to know about to alert their healthcare providers — just as we did with anthrax, watch for these things. They look like a lot of other syndromes that you're familiar with, but we need to watch for these things.

Those are the kinds of things that I think are the full responsibility of the clinical team, and administrative team as well, as we set aside resources to develop those kinds of tool kits, information packets, media blitzes, those kinds of things.

I've recently become aware of an emerging role in the nursing profession — a forensic nursing role. It's a role that helps nurse clinicians develop team assessment and intervention skills related to criminal behaviors and surveillance of unusual events and protection of environment when they have a suspicious event. I just wanted to open everybody's thinking up to beyond the medical community's responsibility in this.

Kristi Koenig: I think you're absolutely correct. In fact, I usually say "astute clinician." I don't know if I said "physician" today.

Cathy Rick: I just listen and I heard it right a couple of times and I know there's a small "m" for medical and a big "M" for medical, meaning physicians versus medical for the whole community, but it is something that keeps us in our discipline- specific, silo-ed, hierarchical nature that gets in the way of doing things.

Kristi Koenig: For example, if you had a patient come in with a contagious, infectious, biological disease, it would likely be the triage nurse or somebody else who first saw the patient. If you wait until the physician sees that patient, then we're going to have a lot more people exposed.

I think it's critical. We're actually working with nursing leadership through our technical advisory committee to ensure that we have that type of training, but, of course, we have a national nursing shortage. The nurses are busy just like the doctors and other healthcare providers, so again, I think we have to look at a lot of automation in our systems, in addition to that training for recognition of those cases where you might be able to see it with just one patient.

Eddie Humpert: Hi. I'm from Durham, North Carolina. North Carolina is famous for Kitty Hawk and airplanes, but we're also famous for pigs. We're the pig capital of the world. I've heard of sentinel chickens and I'm trying to think of, maybe, sentinel pigs. Where I'm headed with this is the Nipah virus, the Malaysian one-mile pig-coughing virus that possibly transmits to humans with encephalitis or whatever. If you were a terrorist, you might not go after the population directly; you might go after the animal population first, and the question is, do we have animal surveillance?

Robert Pinner: I think the answer is, those kinds of threats are recognized. There's some thought to veterinary-based surveillance, but it's not very well developed. That's sort of in summary, my sense of it, but maybe others know better.

Klaus Schafer: There's a lot of interest, at least in starting to do that surveillance, and it's particularly important, one, because of the economic impact — what can happen with animals. But this concept of actually creating a network and doing molecular-level diagnostics, almost using

PCR, was something that Agriculture [Department] actually tested with swine, I believe at Plum Island, and so there's enough interest.

It's starting to happen, but, again, it's one of those areas that probably Homeland Security is really going to start to address.

John Parker: I learned a very interesting fact in the last months talking about agroterrorism, and that included animals. I visited the University of Kentucky — do you know who are the greatest travelers in the world besides human beings? Race horses. And so if you look at the group of people who raise and breed race horses and move them around the world, they are critically interested in this surveillance. And they surveil for the encephalopathies and all of that, so there are niduses of groups of people who are tremendously interested in making sure that diseases don't get into the economics of a business. The economics of horse racing and breeding is in excess of $30 billion. And horses do travel almost as much as we do all over the world.

Not only is the Department of Agriculture getting interested in this, but the Food and Drug Administration also. You know, they have a split role there of who has responsibilities and regulatory capabilities over food and animals at different levels in the production cycle. So, I would say, this type of surveillance is not sophisticated at this point, but the worry is there and that's good because if people are thinking about it means something is happening.

Kristi Koenig: You make a very important point, because we're getting into communities that don't usually talk to each other, and one example is the veterinary community, the agriculture community. In addition to the points that were just raised, we may first see a sign of illness because there's illness in the animal community, so that might be the first time where we detect something that possibly could be spread to humans.

Other communities we haven't mentioned, for example, would be the law enforcement community, which of course has a completely different definition when you say "surveillance," so we don't even have the same terminology. We're probably at a lot of risk for a bioterrorist attack on food, such as what happened with the salad bars in Oregon. This is an area where there are systems being worked on in terms of surveillance, but we haven't really connected everything yet.

Clara Witt: I'm with DoD Global Emerging Infections. Maybe I can try to help add some light to the veterinary aspects. I'm a veterinarian by training. In fact, I guess it was, I just came back from the U.S. Army VETCOM meeting. They have a meeting every year. I was very pleasantly made aware that there's a tremendous amount of discussion and, in fact, activity on the veterinary side on surveillance in emerging infectious disease and active responding to detections. At least 75 percent of the presentations were specifically on that topic.

There are several organizations in the veterinary community, in fact, working also on the topic. The zoo veterinary committees and organizations have a very active surveillance program for detecting new and emerging diseases, bioterrorist activities, and that's supported, to a large extent, by CDC. The West Nile surveillance activities are largely, in part, veterinary supported, and that's a combination of DoD, U.S. Department of Agriculture, the state veterinary communities, and a variety of individuals.

The Department of Interior has been talking with DoD GEIS in working with their resources, wild animals, the wildlife out there. In using these resources as part of a surveillance system, the U.S. Army VETCOM, again, is working with us to use the military working dogs and other government-owned animals as early sentinels for infectious disease events or other detections that may be necessary.

So, there's a lot of germinal activity going on. It might not be as known as one would like, and certainly we have a long way to go to communicate with the human public health side, but it is there and it is progressing quite nicely.

Klaus Schafer: It ties back to one of the earlier questions, and that is all these disparate communities really coming together and providing different parts of the surveillance picture, and what's interesting — there have been some studies that have been funded to start to bring in meteorological data, to look at studies on infections in dolphins, and all sorts of interesting approaches.

Whether it's relevant or not to disease propagation in humans, the work is going on, and I think one of the neat things that Homeland Security is going to hopefully be tasked with is integrating all these different activities into some kind of model that allows them to do modeling and simulation and do

predictive things. I'm looking forward to those activities happening over the next five or 10 years.

Chip Taylor: I'm serving as the medical director for our Navy Medicine Office of Homeland Security. I'm a family physician by training, so I'm one of those astute clinicians.

Following 9/11 we realized that surveillance was an activity that wasn't really occurring in our usual system and very rapidly instituted semi-pencil-and-paper, taking what we do in the field all the time and putting it into the hospital system until ESSENCE was linked in across the system. The issue that I would raise is that there is a seeming feedback loop process that needs to be put into place here. And we're dealing with a situation that I would disagree, respectfully, is not like diabetes.

When people come in to me with diabetes, it's a very prevalent disease. Screening for that in my population is fairly easy. Folks who come into my office with pneumonic plague or to the ER with pneumonic plague are going to be mixed in with all the other folks who come in with acute respiratory illnesses and so forth, and it's finding a needle in a haystack

I would say that the challenge here in primary care is that you are trained to see the horses. The challenge with the ESSENCE is that where we draw the data out of our system we are oftentimes looking several days into the past. Even though we draw it on a daily basis, it's too far up the data stream.

My question is, how do we take the diagram we saw from CDC with overlapping links between local, state, or military and then the federal response and tie in that feedback loop so that we have those trained professionals able to do the surveillance, the stealthy identification, without raising the fear level that this may not be grandma with pneumonia? This may be community-acquired pneumonia. This may be something else.

John Parker: What I talked about in the beginning — the practice of medicine tying in with public health, and the person who is practicing medicine is depending on that great public health system — when he or she reports for work in the morning and turns the computer on and instead of just seeing icons for different programs on the computer, one of the icons is blinking and it happens to be the health alert network to tell you that somewhere someone has picked up a particular disease. That's the astuteness

of your practice, in that you're not putting it out there as a zebra. It's a possibility of the day.

Robert Pinner: Thinking in terms of systems, one of the messages for me is that looking at data and analyzing data while doing national-level aberration detection, that sort of thing is important and has a role. Making data available and looking it — facilitating making it available and analyzing it at a local level and even at a clinician level is an important part of the whole operation.

Thinking of a trip I made to India a few years ago, looking at national-level data in a country of a billion people didn't make much sense. It was only at the very more local level where they would understand that a blip in malaria cases really was related to this water cooling over here or that sort of thing. That kind of texture isn't something that you can easily do over abrogated looks at the data.

Patrick Kelley: You bring up an important point about timeliness, and I would note that as we've studied that with ESSENCE, that is one of the problems we have. I think it's a solvable one, because the timeliness varies dramatically by installation. It's not as though the data always takes two days to get to us or always 36 hours. In fact, some places it's six or seven hours and other places it's a week.

One of the things that we're working to do is to mobilize a big system, to get them to realize that this data capture they're doing is not merely for bean-counting purposes but it is for a rapid surveillance system. But, what you point out is a weakness — and it arises because these data sources we're using were not designed for this purpose. The reporting standards put in place were appropriate for the original bean-counting administrative kind of use, and we are improving that.

Another point worth thinking about is that there's always a role for the astute clinician, a critical role. I might, rather than use "astute," say a "reasonable" clinician. I think there are some people who will have a problem, and a reasonable physician will say, "You're okay." There will be people who have smallpox, will present so early in the prodrome that there would be no likelihood that a normal person would divert this individual to the side. I think that's what we're going after. You can't expect a clinician to divine anthrax or smallpox with the earliest prodromes of both of them.

We're filling a particular niche here under the thought that maybe there are circumstances that a reasonable physician would miss. But, looking at it from a population point of view, you see it as an aberration across the population.

Klaus Schafer: A criterion for all systems that we put into play is that at every level we collect data, we have to give something back to the people providing the data. That's a rock-solid criterion.

I'm a family practitioner myself and so the molecular-level diagnostics — the zebra chip concept is all the common pathogens on a single chip, and embedded in that chip are the threat agents. In the clinical setting, any time you suspect an infectious disease, you would just run a sample and be able to get your results immediately.

If it just so happened, because syndromes tend to come in clumps and be various different diseases, you'd be able to pick out the definitive diagnosis at the point of service, which would be pretty cool. Now, we're not there yet, but just like all these things, they need to be developed and worked over the next several years. We've got to get the false positives out and and work it. That's the future, and that's what's coming, and I'm excited about it.

Kristi Koenig: A couple of additional challenges: One is that we don't always have historical data, so we can't tell if there's a blip because we don't know what the baseline is. That is one of the strengths, actually, of the VA system — we do have historical data that we could review.

The other is, as we talk about building these surveillance systems, I think we need to be acutely aware that another threat we haven't mentioned is a cyber attack. And it's probably a quite realistic threat, that if we had a terrorist attack — let's say a biological weapon — there could very well be a concurrent cyber attack that could potentially bring down these automated or electronic systems. We have to have backup contingency systems for our surveillance collection and reporting just, as we do with electricity and everything else.

Marion Balsam: I'm a retired Navy pediatrician, but I'm here today representing the American Academy of Pediatrics Task Force on Terrorism. My question is, has there been any thought regarding any issues that might

be of peculiar importance to children or of most specific relevance for children — or are you aware of any issues which might need some specific thought that are of relevance to children?

If surveillance discovered something which needed to be acted upon in a timely manner, most children are in the care of someone other than their parents for significant periods of time, so there are of course such issues as privacy, consent for care, or even quarantine.

Kristi Koenig: We don't see children, typically, at VA, but we have looked at some of these issues in terms of community partnerships. Some of the programs in place — as you point out, children are not likely to necessarily be with their parents, at the schools for shelter in place and that type of thing, and these are issues that need a lot more attention.

Another concern is the psycho-social aspect, that if you're going to tell a parent, "We're shutting down the school and we're keeping your kids here until we sort out what's going on," they're probably not going to accept that. They're going to want to get to their children. So, even if we develop authorities, for example, for quarantine, it may not be realistic, particularly when we're talking about potentially separating parents and children.

Patrick Kelley: The whole issue of children brought up to my mind that our ESSENCE system, to be perfectly blunt, was created partly because of the motivation of bioterrorism, but we have been learning a variety of other uses for this. For example, after 9/11 we used it to monitor mental health problems in the community and were able to detect issues in children. In deciding, thinking about national systems, it may be worth seeing these as systems that can provide information to you that goes beyond an early warning about bioterrorism.
We are now, as I said, working with the mental health community to use this as a way of monitoring community mental health after disasters like 9/11 or other kinds of things. We detect outbreaks very relatively easily in basic training settings, and we track children. And if we were able to assign children to schools or to daycare centers, I wouldn't be surprised if these systems would help detect outbreaks in schools and daycare centers.

I think in certain communities it might help track things like heat injuries in the summer. So, as these systems are crafted, we might want to bear in mind alternative uses to make them maximally beneficial to the public health

community, so that even if they are still of debatable utility for this narrow purpose, they might still serve a broader benefit.

Robert Pinner: I don't have anything to add specifically in the context of terrorism surveillance. But there are many intriguing and complex aspects to interaction of the population — children populations and older folks. In the decreases in invasive pneumococcal disease in children in the age group who were being vaccinated, it also looks like there are parallel decreases in age groups over 65. An obvious possible explanation that may be even likely is that children are vectors of infection in that age group and there's interaction there.

Another example that has a bearing on how you think of the information architecture of these systems is in the area of neonatal group E streptococcal disease prevention, where the principal prevention strategy that's effective is late-term vaginal and rectal culturing of the mother and then having that culture result available and ready at the time of delivery, so that antibiotics can be offered based on those culture results.

James Zimble: I'm at the Uniformed Services University of the Health Sciences. I don't want to make your life any harder, but your surveillance systems, as you have described them, start with the health system and at point of service, and it seems to me that there are several data points prior to that. Most individuals who have prodromals don't go to the doctor right away. They go to the drug store or they stay home in bed and have chicken soup, so I think there needs to be some data on absenteeism from schools and looking at over-the-counter inventories and looking at baselines for those sorts of things.

Patrick Kelley: As part of our DARPA-funded ESSENCE II project, in collaboration with the Applied Physics Lab at Hopkins, we do look at over-the-counter sales in civilian pharmacies. We also have access to the military pharmacy data, which includes outpatient data.

Getting back to the timeliness issue, that data gets into a central database in three and half seconds after the drug is handed over anywhere in the world. We have been able to do studies showing how those prescriptions line up fairly nicely with the types of ailments for which you would expect that prescription to have been supplied. We also are, as are some other groups, getting involved with looking at nurse call-line data because, there's really a

continuum. You start feeling sick, you look in your medicine cabinet, nothing's there; you send your spouse out to get something, hopefully she comes back with something; you're not better, you call the nurse; then you go to the outpatient clinic, you're admitted; then you go the intensive care unit; and then you might die.

At all of those points there might be useful things to pick up. That's my emphasis when I said there are complementary data sets there.

The point about school absenteeism is great, and also I think work absenteeism, particularly if you can tie that to a geographic setting. We now are able to, for example, look at the 360 or so people in the military who work in the Skyline building and the 9,000 uniformed people who work in the Pentagon. I really think you'll get much stronger signals if you can tie people in your analyses to where they're likely to have been exposed as opposed to where they live.

Robert Pinner: There's lots of potentially important sources of information which are being evaluated in a number of different ways. The principal issue, though, will be what's the predictive value; what will be the utility of these data. Pharmaceutical sales could indicate illness, but also could indicate a sale on certain drugs.

Kristi Koenig: And there is, of course, a whole additional cohort of patient who skips all of those interim steps and just picks up the phone and dials 911 when they don't feel well, and that's another area we didn't mention. But some systems — for example, in New York City — are looking at data and comparing it to historical data for ambulance runs — are they getting more cases of people with flu-like symptoms calling 911?

John Parker: We can see that as we peel this onion back there are lots of sources of data of all different textures and varieties that perhaps, if converged and fused, give us new types of information. Absences, pharmaceuticals, just the daily electronic billing data that moves from a hospital to the CMS system every night to keep the financial world in healthcare alive all provide data flows to us.

Panel 2: How can national surveillance be made reality?

Ellen Embrey *— Deputy Assistant Secretary of Defense for Force Health Protection and Readiness*

Farzad Mostashari, MD *— Assistant Commissioner, New York City Department of Health*

Julie Fischer, PhD *— Professional Staff Member, Senate Veterans Affairs Committee*

Daniel Sosin, MD, MPH *— Director, Division of Public Health Surveillance and Informatics, Epidemiology Program Office, CDC*

Ellen Embrey:

Truly everyone recognizes that we need to have a national surveillance system. The trick is organizing ourselves in a way that's meaningful and useful to the entire public health infrastructure. I guess the first way to go about that is to actually define the public health infrastructure —all of its parts, not just the PHS, but all of us that contribute to it. And DoD certainly has a very large contribution.

We have about 9 million beneficiaries whom we provide direct care to. We have a variety of surveillance capabilities that we undertake on a regular basis for all or parts of that population. We have a lot to do ourselves, even within our own system for integrating our surveillance into a meaningful superstructure. But, we do have quite a bit of data that we could share. We have reportable medical events on over 70 reportable medical diagnoses. We've been capturing that at the MTF level — the "medical treatment facility." It includes our hospitals and our clinics.

We also have syndromic surveillance capability that the services run at those locations and elsewhere in deployed situations. They capture routine data from health encounters to try to understand what's going on, the syndromic elements of that. They report the illnesses that are reportable, as well as capturing the data that could be used for longitudinal surveillance in a different database that we collect. We have a public health laboratory system through that network, and we're seeking right now to connect to the CDC's laboratory response network. We are working on BioWatch, the President's

initiative to expand capability to diagnose existence of biological agents here in the nation, and we are contributing to that.

We have a deployment environmental surveillance capability, as well as a garrison environmental surveillance capability that includes industrial hygiene information, as well as automated data systems for capturing environmental and industrial hazards. We also have a bit of that while we're in deployed situations, and we capture that through that system. We have a specific deployment medical surveillance system, which is to be ultimately integrated into our standard automated system for the CHCS, our automated systems for capturing all of the data in our hospital system. It is in several iterations of development.

CHCS II is gradually being implemented now. The Theater Medical Information Program contains critical elements of that system and enables us to capture data in a deployed situation and have it transfer effectively and seamlessly back to the garrison where the official records are kept. This is the cornerstone of our ability to have effective medical surveillance in the future, but we're not quite there yet.

For the current operations in the Middle East, we have deployed a surveillance system that captures medical encounter data for all of the deployed forces. It is automated. It captures it in automated bases and retains it. We also collect DNBI data — Disease Nonbattle Injury data —which is helpful to determine whether or not there are bad things floating in the air, so we can respond to that more effectively.

The heart of DoD's ability to capture data about its 9 million folks is the Defense Medical Surveillance System.
It was established in 1997, I believe, maybe earlier, as a defensewide system. It captures longitudinal data across the various data systems I just described. It hopes to be the way that we understand and respond both from a policy perspective, from a clinical perspective, and from a programmatic perspective on how we can better protect and maintain the fitness of our force and their families and retirees and veterans.

So, in terms of a national surveillance system, how do we contribute? We have a lot of data, we have a lot of expertise. Preventive medicine is important to us. We're moving closer and closer to that as our primary emphasis in healthcare in the department and, as a result, we are in the

process now of reorganizing our policies and restructuring our total medical surveillance to include all of the data sets I just talked about.
Right now they're separate systems being managed separately; they're not integrated. There's no superstructure for defensewide analysis of that data. So, if we as a closed system have difficulty in integrating it, then the national system has got that times many.

I think we're in every state. We're in many, many locations around the world. We have a desire to incorporate data outside of our system. In fact, we have many opportunities and situations where we do that now currently, but we need to institutionalize that and work through the appropriate authority — and I'm not quite sure what that authority is — to make sure that the system of surveillance is meaningful and useful to all. It should not necessarily be focused on terrorist or biological agent attacks, though that would be nice to have. The reality is we need to have an infrastructure in place with the right experts to be able to do this for public health.

Having a system that collects data without having a system of analysis and rules for what you do with that data and how you respond, particularly in health emergencies, is the big rock in our objectives. We need to figure out what we need to do with that, and we're willing to work with whoever is responsible for this.

We're willing to work to make sure that we all come to some consensus on this.

Farzad Mostashari:

I'm going to talk about New York City. My position, from having worked in a local health department, is going to be a very local perspective to a national problem. I don't pretend to represent the national, necessarily, big picture, but I think we have some things to share.

First, there's a lot of uncertainty about the term "syndromic surveillance." What I'm talking about is real-time public health surveillance using data that's routinely collected for other purposes. The fact that it's real-time means that it's got to be electronic, and it's data that's available essentially for free, because it's been collected for other reasons. There's no dedicated

public health data collection system that's set up for it, and this induces some of its own idiosyncrasies.

Our goals are, yes, early detection of large outbreaks but also — I don't think that's the only goal —characterization of the size, spread, and tempo of outbreaks once they are detected. I think that's also important, and we shouldn't put all our hopes that this is going to be the system to detect bioterrorism. But even it's not, I think it can have some value. Also, simply monitoring of disease trends in real-time can be quite valuable.

There are a lot of potential data sources out there. If you follow the course of a hypothetical person who, say, has inhalational anthrax, they may feel fine the day after exposure, on day two they have headache and fever and they buy Tylenol. If that could be reflected in pharmaceutical sales, that's a potential data source for syndromic surveillance. Day three they develop cough, they call the nurse's hotline. Day four they see their private physician, and they may call in sick from work. They're given the diagnosis of flu. On day five they may worsen, they call an ambulance, and they're seen in the emergency department. All those are potential data sources, and I think all of them are things that we've looked at one point or another above that dotted line.

It's day six when they're admitted and given a diagnosis of pneumonia. Day seven they may be critically ill in the ICU, and on day eight they may expire. All those are instances when traditional surveillance might be expected to take place, with the goal to move our detection up as much as we possibly can. Obviously, there are a lot of potential data sources.
We have data showing the flu season from a year ago from four different systems. Included are EMS calls, and we have the ratio of respiratory to all ambulance dispatches. In the data, there's a certain time around December 29th, when it goes above the bounds that we would expect above the threshold, and it stays up there for a few weeks, and then it comes back down within the bounds. That happens to coincide with the peak of influenza season as determined by influenza isolates received at World Health Organization reference labs.

The same kind of shape is seen in emergency department respiratory visits and subway worker absenteeism for flu. A little bit later come pharmacy antiviral prescriptions.

Our data aren't limited to just respiratory or inhalational sources. We also have been using this to monitor for diarrhea and vomiting outbreaks. We've detected outbreaks this way, and we have actually sent out press releases, notices to physicians. Our first indicator of the very large wave of calicivirus outbreaks that occurred in New York City and elsewhere in the country was through our syndromic surveillance system.

That's just an overview. Those data are all temporal, and I just want to mention that we also look at things in space and time. We had a real test of this — a real life test of this, unfortunately — November 12th, 2001, when an American Airlines flight crashed in the Rockaways. The next day we did our routine analysis, and there was a very strong respiratory cluster centered exactly on the crash, both in zip codes and in the two hospitals that flanked them. Twenty-seven observed; I think there were 10 expected.

So great, you have the system, you have nice ways of getting the data in, you have nice ways of analyzing the data. But what do you do when you see them? That's a really key issue, that I think because of our position as being both an innovator of syndromic surveillance and a local public health department responsible for investigating — I think we've had a lot of experience in this.

It's very difficult. It's the most difficult thing about syndromic surveillance, because, if you think about it, syndromic surveillance is all about non-diagnostic data. Our goal is to detect an outbreak, to diagnose an outbreak of what's causing this, where the information we're receiving is non-diagnostic. So, the first question is: Is this a true increase or is it just natural variabilities as a statistical fluke? If you set your P value at .05, five out every hundred days you're going to see a .05 alarm. So, that's the first task.

The second task is, we've convinced ourselves that this may well be a true increase in illness, but is it naturally occurring or is bioterrorism? Frankly, if it's naturally occurring, of limited public health importance, we don't care, and we're not going to pursue it much further.

What are the tools at our disposal? The first thing we do is we try to drill down in the data, and different data you have a different ability to drill down into it. Basically, if we're looking at aggregates, we may want to break them down and say, "Look at the line list. Who are the people who represent this

signal? Are there a lot of miscodings in that? Is it something that really is not the kind of syndrome that we're interested in?"

In term of whether it's a true increase or a natural variability, one thing we do is we try to get a half-day log for the day that we're currently in to see if the increase is sustained or not. You would expect if it's just a statistical fluke, more than likely you would go back down, whereas if it's the leading edge of an outbreak, it would be more likely to continue to rise. That's a key factor we use in our decision analyses — where we can get that data on a timely basis.

If we still are not comfortable — and this happens a few times a year — we then query clinicians and laboratories, ICUs, the admitting resident. We have twice now actually gone to the hospital and done chart reviews of the people who comprised the signal to see if there was anything abnormal, although you may not expect anything abnormal in the initial prodrome. We actually called people at home and said, "You were in the emergency room yesterday with a flu-like illness. Are you feeling, better or worse?" Ultimately, though, we need to get increased diagnostic testing, and this is very difficult.

When we had the large GI outbreaks with hundreds of cases, it was like pulling teeth to get two stool specimens tested — to find the calicivirus in both. So, this is a key challenge, and I hope that there is some federal assistance and enhanced diagnostics for this.

That's our local system. It did not rely on a national surveillance system. If you look at the different elements of it, we have an operation ambulance dispatch, emergency department visits, and subway worker absenteeism. None of those is likely to be part of a national syndromic surveillance system. This is local data for the most part.

But it's very tempting, isn't it, to think of jump starting the process. Instead of waiting for a hundred New York cities to develop and to get going and hope that this all turns out for the best — there's national data out there. It's available. There's pharmaceutical data. There's health plan data. There's nurse's hotline national data. Why not just aggregate that national data, maybe get some local data also? Make a big centralized data warehouse, and do data mining for aberrations in the data.

That way, we could have a — I call it Transcontinental Analysis Nerve Center, or TANC — that will take care of it. We'll have a national syndromic surveillance system.

I'd like to raise a few issues. The first is a legal mandate, and for some data this is not an issue. If you're getting pharmaceutical data that's being sold to IMS anyway, you don't need a legal mandate for that necessarily. But for a lot of the other work we do — when we have potentially named patient clinical information — you do need a legal mandate to do that. We feel we have a legal mandate.

There was a passage in the New York Sanitary Code that says "Local health officials shall exercise due diligence in ascertaining the existence of outbreaks of illness or the unusual prevalence of diseases and shall immediately investigate the cause of same." There's a lot of wisdom in these old laws, and it's not an accident that they put the legal mandate to investigate and the legal requirement next to each other. So, we have the right to collect the data because we have the responsibility to respond, and that would not be true for any national center.
You can't make up for a lack of local capacity by making a national analysis system. Smoke detectors need responders. I think there's a real danger about a false sense of security.

We have 80 percent of the nation covered when we really have nothing covered, because signals come and go, and e-mail maybe is sent out, and there's no local capacity. This is not a way to get around a lack of local capacity. I think could be a mirage. It's also prey to multiple comparison issues. If you're doing analysis for a thousand different towns, villages, cities, whatever, every day you're going to find alarms. So, we shouldn't think that this is going to be a rare — that finding alarms is going to be a rare event. Somewhere something's going to happen, especially when you start looking at multiple data streams or any kind of aberration.

A problem that I'm very concerned about is that it's a little early to be setting sail on a big ship that may be very hard to turn. I don't think we know the best practices yet in terms of data sources, data analysis. We've been doing some work on something as simple as grouping ICDs into syndromes. And it's complicated, and there's a lot to it. If we lock in really bad choices, it would be very difficult to go back.

If we're telling data providers, "Just give us the total number, the aggregate number of visits that were in this group" — once that's been set in place, it's not going to be easy to go back and break that down and reformulate it. I think one of the major advantages of doing this at the local level is that we can really get the benefit of dual use.

I don't know if 10 or 20 years from now we're going to judge whether the syndromic surveillance for bioterrorism has been a major success. I don't know if we're going to continue to think that this is the way to go. But I have no doubt, no doubt whatsoever, that the use of existing electronic data for public health surveillance is here to stay. Not for bioterrorism necessarily, but for everything else.

For example, at the local level we had an increase in the cigarette tax in New York City, and we were able to track the sales and nicotine replacement therapy. It was great to be able— within days of the tax increase going into place — to see there was a 30 percent increase in nicotine patch sales. That's not something we're going to be able to get from a national surveillance system.

I think there is a problem of over reliance on national data services, which may not be the best data sources. For local public health and public health surveillance, the best source of data is clinical data — not pharmaceutical data, not some of the data that's more available nationally. For a lot of those, unfortunately, you still need to do that local one-on-one, because the clinical information systems are not in place yet, other than in the military.

Most concerning in terms of national security is that this [national system] could introduce the single point of failure. If it's the wrong approach, there may not be enough redundancy in the system, and it could be also vulnerable to physical disruption or cyber attacks.

So, how do we build the national highway system? If you look at our hospital emergency room data flow, we have basically for every hospital a different system of receiving data. In some parts of the country the information systems are more advanced, and they can plug into some more standard solutions. But in New York City, we found that we really have to go one by one by one by one — and that's just crazy, right? I think a lot of the good work that CDC has done on national standards for data transfer and groups like the e-health initiative is right on.

I'm not going to pretend that it doesn't make sense for CVS, instead of negotiating separate MOUs and giving data individually to 50 different cities, for CVS to give its data to one national broker and that broker then distributing data to locals -- I think that makes a lot of sense. I think that's fine, as long as the data elements, the granularity in the data that the locals want both in terms of product and zip code-level data is preserved. Because once CVS is giving data to the national broker, we're not going to be able to negotiate a separate relationship with them. They'll say, "Well, just go get it from them." There's a risk of, whatever systems are set up, limiting the ability of locals to get the detailed data they would like.

Ultimately it comes down to strengthening local capacity. There's just no way around this, and for that we need not necessarily a flood of short-term funding but reliable sustained funding. *Reliable sustained funding.*

Is that not enough? Not enough for the federal role? I can give you a few more. Evaluation metrics. There's a lot of different -- a lot of good work that's being done out there, a lot of different flowers are springing up. But if we're to really move the science forward, we need to have more of a winning approach.
At some point we need to say what works and what doesn't work. There are vendors out there, hundreds of them, who want to get on the gravy train, and local health departments don't have the time — itis not an efficient use of their time to have to take hours out of their day to meet with vendors who want to tell them how their latest system is the be all/end all. So, it would be great if there were an evaluation center, a consumer reports center, for evaluating a vendors clearinghouse.

Information exchange — people working on syndromic surveillance systems being able to talk to each other in a setting of a trusted convener, such as the CDC. Making that link between "we think there's an outbreak going on" and being able to determine is this bioterrorism or naturally occurring is very difficult, and rapid diagnostics could be very important in that.

Here's a big project: Electronic clinical information systems. There are many of them out there, but the average community health center in New York City, the average doc doesn't use it. And if you're talking dual use: To have an electronic medical record, to have a system of patient reminders and provider prompts, electronic billing, quality assurance and performance

indicator reporting, as well as the ability to provide data in the standardized format for syndromic surveillance and reportable disease.

That would be amazing. That would be great. And if the federal government would do everything it could to further that, whether it's through funding for research and development, whether it's through their contracts, whether it's through incentives, whether it's through legislation -- that would be a big project worth building.

Julie Fischer:

I'm going to begin with my standard caveat, which has become my mantra. I'm going to talk about the congressional perspective on national surveillance, and what I want everyone to remember is that there is no such thing as a uniform congressional perspective. It sounds flip, but when one discusses how Congress feels about a specific issue, Congress is two houses with a lot of committees and subcommittees on each side since reorganization — including at least one more appropriation subcommittee on each side for Homeland Security.

We have political issues that divide us, and at any given time one-third of members of the Senate are running for reelection, and at any given time every member of the House is running for reelection. And that makes an enormous difference in perspective.

I can give you a snapshot of what is happening in Congress, but I can't give you a congressional perspective on anything. In terms of medical surveillance and congressional perspectives, we have a tale of two constituencies. W have military medical surveillance and domestic medical surveillance. I would say that the history of Congress' interest — interest as we see it now — in military medical surveillance dates through about 1991, when service members returning from the Gulf began to describe a set of disparate symptoms that many attributed to their service.

This became a very highly charged political issue. A lot of individual congressmen became very angry when they felt that constituents returning to their own districts were not receiving the attention they felt was due. There was a lot of agitation within Congress to do something, to define a Gulf War

syndrome, to label its symptoms, to create benefits in healthcare that were appropriate. In the 10 years subsequent to that, Congress has shown no reluctance whatsoever about telling the military how to do medical surveillance — at the very fine level. There have been upward of 50 hearings on medical surveillance on both the House and the Senate sides.

There are actually two committees on the House side in addition to Appropriations that have jurisdiction over this. So, you get two of everything over there that you normally have. And because this is an issue that touches individual representatives and senators, there have been a lot of individually motivated bills that have not come directly out of the Veterans or Armed Services committees.

In terms of military medical surveillance, what Congress demands is very clear: One hundred percent coverage of everything. It's a little more difficult than that in enactment, but Congress has again not been shy. Legislation was enacted in a defense authorization bill. I believe in 1998. that mandated collection of health information predeployment, during deployment, and post-deployment, requiring a level of exams which has been interpreted as screenings requiring collection of information during deployments that can be then in some way passed on to Department of Defense healthcare givers and subsequently to the VA. In terms of military medical surveillance, Congress is quite clear in what it wants.

In terms of public health surveillance for domestic issues, Congress has not been quite so clear, and I would say that the history is much shorter. While we've been wrestling since '91 with what we want out of the defense surveillance system, I would say that real awareness throughout the majority of Congress about public health infrastructure and surveillance issues dates from October 16th, 2001. So, there is much less history.

Prior to that date, we had a bill that is generally referred to as Kennedy-Frist, which passed in 2000, expanded the Health Service Act, and put a little bit more money into the system largely for CDC to expand the programs that it had in place. To say that it was "generously funded" would be over generous. It was more than we had seen previously, but not a tremendous amount of money.

Suddenly, following the anthrax incident in Senator Daschle's office and in over five days approximately 6,000 congressional personnel lining up for

nose swabs that they felt were diagnostic, there was a lot more awareness and interest in public health issues. The driving force is not really public health as we previously defined it, but biodefense. The discussions that ensued, which ended in Public Law 107-188, the cumbersomely named Public Health Preparedness and Bioterrorism Response Act of 2002, largely focused on funding that devolved to the local level.

There was a lot of description about what we'd like in terms of biosecurity. There was money assigned to the CDC for desperately needed infrastructure repair and for expansion of existing programs. But a big, big chunk of the change in that bill, $1.1 billion, went to the states. Dr. [Donald] Henderson did an amazing job turning that around quickly and getting it to the states. But Congress did not put a lot of detail in as to what they wanted done with that money. I think that's a result of a philosophical debate within Congress. 107-188 did not require or describe a national surveillance system. It didn't even create requirements or standards for state surveillance systems. It asked the states to take the money and plan something. That decision did not arrive out of a uniform wish to do so. There's a lot of wrestling internally about, do we set benchmarks? Do we tell the states what we want? Do we tell the states what to do? Or do we give them the money and tell them to go forth?

That was the decision that's finally triumphed, so that the locals make the decisions on what is locally needed. The reason for that was the awareness that the public health infrastructure had become so decimated, had wasted away through lack of resources for so long that mandating a national standard might be a pointless exercise for states that were so behind that they could not meet the national standard.

The quote that was used in conference by an unnamed staffer was that "Demanding any sort of syndrome surveillance or national surveillance capacity would be like putting a Porsche engine on a wheelbarrow." We didn't, in the Homeland Security Act, really elaborate on that much further, except to further muddy the waters about who's actually in charge.

There is a lot of transfer now of authorities for emergency preparedness and medical emergency preparedness and public health issues that I think will take a couple of years to sort out. It's not a terribly well-defined assignment when you say HHS should work with DHS to determine what's necessary,

and I think that that will take a little while and will probably be, to some degree, personality driven at that department.

Does this mean that it's all over, Congress is done? No. There are bills right now that had been introduced early in this session that mostly address the demand for sustained funding. There are currently bills introduced in both houses that authorize money for the existing initiatives that have already been passed into law. More money, continuing money. I think all of them are on the order of about $1.5 billion for states and a little less than that for ongoing CDC initiatives. I think that there are questions that Congress needs to answer before we go any further, and those are questions that people in this room need to help Congress answer.

The first is, do we need a nationwide surveillance system? And the second is, if we do, what does it look like and what do we expect it to do? Is it going to be an issue of national defense, or is it going to be an issue of public health and individual welfare? Because those are very different goals and don't require the same statutory authority.

If we wish to bring about a national surveillance system, we need to answer what Congress actually needs to do — we've talked about legal initiatives, but the truth is that not all these require statutory authority; some of them do. Keep in mind that the agencies that look at public health through HHS and fund Medicare are are overseen by different committees in both houses. So, you cannot say, "Let's have a CDC initiative to have hospitals get paid a dollar through Medicare every time they report a reportable disease" without a pretty profound statutory change.

You don't have to have statutory changes to ask CDC to put together a national surveillance system that collects information from states. I think that if we need a national surveillance system the states, CDC, HHS, and DHS need to identify what the barriers are to that system and what is desired. What do they need to make what they want a reality? Because until Congress sees a demanding need, it will not muck around in the constitutional right of the states to be in charge of their own public welfare.

We have to have a cost and a model. I mean, maybe HIPAA is the model. Maybe we need to attach information standardization to money. But again, Medicare and public health are funded by different committees.

I think that in Congress we have a lot of fledgling awareness of what the problems are. In late October of 2001, there were people saying "public health infrastructure" in sentences who had never heard the words used together previously. So, the awareness is there. And there is an honest desire to do something. Right now the thought is that the money is best used on the state and local level, until the need is delineated s to what must be done on a national level. And DHS again is going to have to drive a lot of this.

I would end this coming full circle — being cautious about thinking of things as a uniform seamless whole — and warn you that just as researchers and clinicians tend to think of Congress as a seamless whole, most individuals in Congress draw no distinction between the clinical community and the public health community. They tend to think of them as a seamless whole.

The strategy right now is to rebuild public health, and the thought is if we give money to states that will happen. But that really depends on individuals at the state and local level reaching across chasms that have grown traditionally between disciplines to link together all those disparate communities — not only clinical medicine, public health, but also the nontraditional ones we've discussed here p, such as agriculture, mortuary services, emergency response, schools, the elements of syndromic surveillance.

All of those together will require a lot of reaching out at the local level, because Congress tends to see them as a seamless whole. So, if you want something different, there's a lot of education needed.

Daniel Sosin:

I have two main take-home messages. One: How can national surveillance be made a reality? National surveillance is a reality, and that's my one starting point.

Number two: As we think about how to supplement national surveillance, there is a need to focus — when we're thinking about detection capacity as opposed to surveillance in the midst of an event —as closely as we can on

the clinical environment. A lot of this exploration that we're doing is meaningful. It's important, and we may learn a lot, but our experience so far is, the specificity that comes as you get closer to the clinical environment is very important.

I have a headache, my heart is pounding. It's because of the urgency of this issue, the range of opportunities around this issue. The excitement is so great, and the range of things that we're talking about here is so expansive that it's really just hard to get your hands around.

But, there is a reality of a national surveillance system. Perhaps it's the core of what it is that we're going to build on. Certainly there are limitations of this system, and there are many things to address even beyond the technical solutions and the advanced technology that we can bring to bear here. There are ways to improve the exchange of information, the relationships that we build between clinical medicine and public health. But it's a place to start, and if we start there maybe we can get our hands around the rest of these issues as they come up.

Our national system starts with the national notifiable disease surveillance system, which is our reportable infectious surveillance system in this country. The military is a part of that just as the general clinician, the nurse, the physician — all the providers who are expected to report. This is a state jurisdiction. In some situations it's a local jurisdiction as well, but the jurisdiction for being responsible for collecting the information, responding to the information, is at a state level. It's built from providers reporting to the local level and then to the state — the local to the state and the state to the federal level.

CDC supports this national system by addressing the standards that are needed. What are we collecting? What is the case definition for those things that we're collecting? What are some of the data interchange standards for what we need to collect?

This is a voluntary system, yet it's very effective as a voluntary system, because at each level there's an understanding and appreciation for the value, the broader value, to contribute to looking at and addressing issues at a national scale, even though, again, the response capability and the responsibility are at the local level. So, instead of asking how to make it a

reality, perhaps the question should be, how can national surveillance be improved?

To address improvement I would say we should focus first on clarifying the purposes — what is it we want to improve national surveillance for — then consider models, and then, obviously, effect changes, and there's not a whole lot of great science on effecting changes. You've got to get out and do something.

Why a national surveillance system? There are many purposes for a national surveillance system. We need to track transient disease so that we can address priorities, we can make priorities, address those priorities so we can address what longer term and broader public health issues need to be addressed. There are needs to monitor the evolution of a natural history of diseases, but clearly what's been driving this interest is the ability to detect outbreaks, and specifically outbreaks that are related to terrorism.

Given that background, how do we detect these things as quickly as possible? What are the national roles for outbreak detection? One could argue that earliest detection is one of the purposes for this kind of a system. Early detection for sure. But is the national level the earliest detection? We have to know first at the national level so that we can get our whomever out in front of the cameras before CNN's already got it, because they picked it up at the local level.

As we think about the reasons why information flows in the direction it does, perhaps the overriding issue for a national system is not to be the first place where this is detected but clearly to be early on in the process. However, there are some appealing ways that national surveillance can support the local response and the state response. Monitoring across geopolitical boundaries is obviously one that has appeal. And outbreaks do not necessarily occur within a geographic boundary, within a community jurisdiction, and we may pick these things up earlier by having the ability to look across jurisdictions.

The efficient distribution of data can sometimes be made as a case for having a national system through which state and local are fed through that national system. Just to step back for a minute on the cross-jurisdictional outbreak issues, there certainly is appeal to this notion that a national system can view across the range of information that we collect for health

surveillance to be able to detect outbreaks that cross jurisdictions as early as possible. But, we have to remember that data signals require confirmation, and that when we're watching data, that alone is not enough. This whole notion that we could potentially automate and remove what's between clinicians' ears any time in the next few years from the process of helping us understand whether this is important or not important is really a fallacy. We need to supplement what can do. We need to automate where we can and improve their access to information as best we can. But there's a whole lot of computing power between their ears that is critical to our ability to understand, to detect outbreaks, and respond appropriately.

So, detecting signals is a piece of it, but then there is a response that has to happen, an investigation that has to follow. Usually that requires some ability to identify personal identifying information, and the jurisdiction for that is local and state. We need to be sure first and foremost that that information is available at the local level. Ensuring that there is timely communication of information between levels of government is really the key place to focus.

In the traditional information flow in the system, a health event occurs, it's reported to local health, who reports it to state public health and then to the federal level of public health. There are many ways to improve the timeliness of information exchange between these levels to ensure that once it arrives at local health, there's near instantaneous turnaround of that information being available at the federal level. We certainly need to invest in defining standards, invest in the ways to get that information exchanged readily between all appropriate levels, and it's not just federal public health but there are obviously, in this realm, a broader range of entities that need to have this kind of information.

A case can be made for doing some of this data intermediary kind of work where there's national data. A national retail data resource may be an important function that can happen at the national level, the federal level, with important sharing of information needs to the state and local level for response. So, we can improve the structure, the architecture for information exchange, but, again, I come back to we're building on an existing national surveillance system.

Where are the models? To explore where ESSENCE — and other models — is working and where it isn't working in a more idealized situation than we have in the general public health system or clinical information systems is an important place to get models and get experience. That we don't have exactly a uniform information system in the domestic or civilian surveillance scenario is an important limitation of the federal system in its entirety as a model, but there are complements that are important to consider. We have a variety of ways of looking at public health — data models, conceptualizing and building architecture around it, weigh information exchanges. The public health information network is a schema for information exchange in a smart way.

There is a variety of private sector models, be they academic or commercial, that we need to understand better and need to invest in to understand better. That consumer reports approach Farzad mentioned is no small task, but it is clearly critical, because not only are those same vendors going to each and every one of these cities, they're going to every state and then all to the federal agencies as well. We need to understand better where to be investing.

For me, trying to look at a holistic model, a national surveillance system, what is the model — let's pick one — is wholly unrealistic. I think it will be very hard to choose a specific system per se, but it is helpful for me then to break down into components, and this is nothing new. The components of early outbreak detection include real-time electronic data exchange, not just syndromic. It's the clinical data; it's the laboratory data; it's making sure that we have information as quickly as it is available, that it's available to public health.

Data coverage: Increasing our ability to detect, is based on the sensitivity that we're getting as much information as we can, the opportunity to connect to the clinical community. I would argue we are never going to get to the point in the detection phase of detecting terrorism or outbreaks in prodromes at the clinical level, that clearly there is going to need to be a need to aggregate data to be able to understand those signals. Pneumonia is pneumonia until we have more information.

A national system for surveillance isn't just about data exchange; it's about this relationship we're building between public health and clinicians. New York City is a dramatic example of how these events have supported a much

stronger relationship between the clinical community and public health, which is very important for intra-event and will be important to the early-as-possible identification of known diseases that we need to have brought to our attention.

When you move beyond data coverage — when we have multiple streams of recognizing patterns, how do we make sense of that? How do we actually determine what is something we should respond to?

Evaluation and performance testing: If we're talking about bioterrorism, we're not going to have many opportunities of real data to test these systems. We need other mechanisms to test these systems, and groups like Pittsburgh and New York City and DoD are working in those areas as well. Adequate capacity at the local state and federal levels to investigate these signals is really a critical place.

We need to invest in research and development. Picking one system at this point in time is not a smart decision. We need to have more opportunities to see what bubbles up. Investing in that pipeline and making sure that we're learning and not locking in to a given system at this stage is important. Connecting all the pieces is a piece that we can move forward on now through standards and through the infrastructure building that's been mentioned here.

Investing in investigation and response capability: This is putting people on the ground, smart people, looking at these data. As in New York City, it has to do with the people who are sitting there day in and day out and looking at these data. There is an opportunity to automate some of that as we learn more about it, but right now it's very much person intensive.

Again, distributed work is critical. There's so much work to do. You can't say this is for DHS or this for HHS or this for DoD. Everybody needs to be in this business and looking at it, and therefore we need to make sure that we coordinate and collaborate. This information can be shared and exchanged and advanced to the day someday when we have enough understanding of these systems that they look like a hundred-year-old existing national surveillance system, that they're just fairly routine and we've automated many of those functions.

Discussion

Mike Ascher: I'm with the University of California and currently acting at the Department of Homeland Security as medical advisor. There is a Department of Homeland Security interest in this problem. We're looking at a little bigger picture with integration of all the air and other programs that are going on and trying to figure out the relative weights and importance.

As a laboratorian I have a question and a comment. A comment was raised that we're finding a needle in a haystack. I very much object to that, because we have a haystack that's full of needles. And I think Congress might learn that. It might be of benefit to explain to someone that as you're looking for plague in a community, in community-acquired pneumonia, you have hundreds of cases of community-acquired pneumonia with no diagnosis. Presumed to be pneumococcus. Some of them die, some of them live. You have hundreds of cases of encephalitis. I think Marcie Layton [of the New York City Health Department] estimated in the background of West Nile there were 600 undiagnosed cases. So, to take the message to Congress we're worried about the plague hitting somewhere at the same time.

In the aggregate we have hundreds and hundreds of fatal illness of unknown cause that are eating at our system all the time. Huge expense. Huge impact. But we're not really doing the best job on that. If you're ever going to sell lab work, it has to be done on that basis. I'm not going to go out and collect samples from those hundreds of pneumonias to test for plague. That's not justified. But to do it right through a chip or something else is very attractive, and that's, I think, where it has to go.

At this point it is really confusing, I think, to people who don't understand that there's tons of needles, and the approach to just put all the haystacks together doesn't tell you very much, because we already knows there's tons of needles.

Kristi Koenig: I have a question for Dr. Fischer. I agree with you that there's some unclarity with the transition to DHS in terms of who's in charge of what piece of things right now, particularly between DHS and HHS. How do you see this playing out, specifically with surveillance, in terms of getting

that clarity? Is there likely to be new legislation or regulations or — what's your prediction?

Julie Fischer: I think that right now that is hard to predict. I do not see on the horizon a lot of very detailed clarifying legislation that assigns individual roles in DHS right now. I think that it's going to take a couple of years of sorting out, and I think that most of the functions for everything we're describing are going to remain in their home agencies right now.

We're not going to put DoD surveillance capacity into DHS, and we're not going to put VA's clinical capacity in the DHS. We're not going to put CDC's functions and abilities into that department. It's going to affect how all of them work together and, I hope, play a role in coordinating the way they interact. But I don't think anyone in Congress expects that those functions will transfer into DHS.

I also don't think that Congress is convinced that the only purpose of surveillance is biodefense. But, I would say in the past two years that's how most of what is being proposed has been framed. There's a lot of interest in dual-use technologies on the Hill as well, and Kennedy-Frist I is all about public health in its purist sense, community detection of disease and prevention of illness and injuries. But it's also kind of, be careful what you ask for.

Biodefense became a windfall-looking thing. It's a moving train. It's going forward. We can all hitch on and bring some money into the public health system. It's like that first paragraph in your grant when you explain the international significance of what you're doing. Everyone's grant, regardless of what tiny protein you study, it's going to cure cancer; it's going to cure mortality; we're going to live forever; people in many countries will stop suffering. By saying that we have dual-use technologies but the most important thing is detecting bioterrorism, we risk focusing all of the resources on the bioterrorism end. I hate to sound pessimistic, but if there is, good Lord willing and the creek don't rise, not another bio-attack in the next five years and we make all of these things biodefense oriented rather than public health oriented, that funding pool will dry up.

Al Buck: I'm from AFIP. I'm going to risk asking for something. I know that's dangerous. I come from the perspective, as many in the room share, that the experience in the federal sector is a good one, by and large, an

important one, and in fact should be exploited to inform the debate about this subject. From what I've heard today, which has been, again, a very exciting, stimulating meeting, it seems to me that there's at least one pilot opportunity that has really not been mentioned and begs to be done, in my view, and that is to take this chip technology and move that into the TriCare arena.

Immediately there are hands up, with all kinds of policy issues and so on, none of which, in my opinion, is insurmountable. To move this on a pilot basis into TriCare communities that are away from military posts, are supported by modest financial commitments, and yet leverage the existing infrastructure and capacity within the military and VA systems to me, as a taxpayer, Joe Citizen here, makes all kinds of sense. I offer it and I would request it.

Ellen Embrey: I think anything that improves our ability to understand and respond to the various indicators of the data we have is useful. Another pilot at this point would be, I think, counterproductive, because I believe very strongly that we need to, as a community — at the federal level, at the state level, at the local level — define the architecture of surveillance. Not just the reportable disease, but what is surveillance in the context of surveillance objectives.

It could achieve some biodefense objectives, but I think it has much better, broader objectives for the medical and clinical community, because it helps us define what our laboratories ought to be able to do, the skill sets of the people in those laboratories, the connectivity between the various players in the public health infrastructure. It could help define the role of the private medical institutions of this country that opt out because it's not profitable.

We have an incredible job to do, and a pilot project is not going to help us. The pilot should be defining the architecture and who are the players and defining the objectives of what surveillance should be, because there are viewpoints at the local level that are different than at the regional level. AIf we're going to manage things, we need to manage them probably regionally in terms of infectious disease, in terms of response. So, our systems ought to be dead accurate for the local people to respond locally, for the regional people to respond regionally, and for the nation to respond as a nation in terms of logistics and other areas, bringing to bear the resources necessary to assist, whatever the cost, manmade or otherwise.

I think the architecture is important to do now. We can do that without acting with a single system.

Daniel Sosin: Two of these questions were about laboratories and laboratory specificity that comes by having a diagnosis rather than a fairly nonspecific syndrome. There are opportunity costs related to investing in a chip technology, for example. If we didn't have to worry about that piece, there's no question that most outbreak detection, through the kinds of systems we have now that are specific enough for us to want to respond to them, come from the level of specificity of the detection site — come from the level of specificity that we can get from the laboratory, whether they're the chips or something else.

There is another piece of managing outbreaks, which goes beyond that level of specificity, but for rare events where we need specificity to detect these outbreaks that we're going to want to respond to, it is an important area to focus on. There are just large opportunity costs if we go down that road.

Mike Ascher: These high-burden things like community-acquired pneumonia that's very severe and kills people every day are not looked at because it's considered not possible. I think if we started with pathogen discovery in that environment, then you would have an opportunity to attack that problem. Then you'd have Congress saying, "Wow, I didn't know I had 400 people die in a year of unknown respiratory disease and now CDC has found another hantavirus." I think that's really an important way to parlay this from biodefense.

Nancy Tomich: My question is, who's going to play the role of consumer reports? Is it going to be DHS? Is it going to be CDC? Is it going to be DoD and VA involved as well? Is it all of the above? Is it at a lower level? Just who's going to make these determinations?

Daniel Sosin: I think the easy part is producing a consumer report. The hard part is figuring out what are the elements of what you actually measure to consider it a consumer report.

This is the place where many of the people in this room and many of the people on these panels are trying to work through what are the issues; what are the standards; what are the ways we performance- test these tools or

these systems? We have some way to go on doing that, but I think it is an all-concerned issue as opposed to some one group needs to take the lead and just do it.

John Parker: The panels this morning have talked about a very large situation that has spanned healthcare and public health for this nation, and bioterrorism has brought a focus to this. If you look at Dr. Ascher's comment about many needles in the haystack and you look at "we do have a national reporting system, surveillance system," we have things here and there — there are just tremendous opportunities, because if we approached what might be very crude medicine we practice today and practice it with the needles-in-the-haystack approach, we might improve the practice of medicine and we might learn a whole lot more.

The other part of this is that I don't think someone has to make a decision about a system. I think that's an impossibility; it's an impossible thought.

The question that needs to be deliberated is, if we were all CEOs of HMOs and the President said, "Will you let me have data from your system if I protect your patients and I protect your business?" — if those questions could be answered on the Hill and a law would say that the CDC can have that data provided, it doesn't invade a person's space or a business intellectual property right or something like that. There are commercial off-the-shelf technologies today that can tap into your data — I don't care what kind of system you're using —into your data, converge it, fuse it, and bring it to a watch board.

Really, I think Congress does have a major role to play here by saying and crafting a law that says the Secretary of Health and Human Services, through his executive agent, the CDC, has a right to tap into your data if you're providing medical care.

John Zapp: I think the lack of clear-cut conclusion of the morning's discussion from a number of national experts speaks to the nature of the issue — that it's one that needs to continue to be addressed.

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